II. REQUEST FOR RECONSIDERATION UNDER 37 C.F.R. §1.111

A. Status of the Claims

Claims 10-32 were pending in the case at the time of the Action. Claims 10-32 have been amended. No new matter has been added. Support for the amendments to the claims may be found in the specification and claims as originally filed. Claims 1-9 are canceled herein as drawn to non-elected subject matter. Claims 10-32 are now pending in the case and are presented for reconsideration.

B. Rejections Under 35 U.S.C. §112, First Paragraph – Enablement

Claims 10-32 are rejected under 35 U.S.C. §112, first paragraph as not being enabled by the specification. In particular, the Action asserts that the specification is enabling only for a method of bombardment of embryogenic maize cells in the form of callus or suspension cultures that have been derived from immature embryos for the production of transformed maize plants, but not any other regenerable maize tissues.

In response, Applicants first note that the claims are not directed to the use of any cells, rather the claims require intact regenerable cells. This subject matter has been fully enabled. The Action itself acknowledges that the specification teaches obtaining whole, fertile transgenic maize plants following the bombardment of regenerable embryogenic cells in the form of callus or suspension cultures derived from immature embryos. It is submitted that these examples alone fully enable intact regenerable cells and no reasonable objective basis has been provided to conclude otherwise.

First, it is settled that enablement must bear only a reasonable relationship to the scope of the claims. *In re Fisher*, 166 U.S.P.Q. 18, 24 (CCPA 1970). Moreover, the Federal Circuit has stated that "[t]he enablement requirement is met if the description enables ***any*** mode of making and using the invention." *Johns Hopkins Univ. v. CellPro, Inc.*, 152 F.3d 1342, 1361 (Fed. Cir. 1998) (emphasis added) (quoting *Engel Indus. Inc. v. Lockformer Co.*, 946 F.2d 1528, 1533 (Fed. Cir. 1991)). This is echoed in the MPEP: "[a]s long as the specification discloses at least one method for making and using the claimed invention that bears a reasonable correlation to the entire scope of the claim, then the enablement requirement of 35 U.S.C. 112 is satisfied." MPEP 2164.01(b) (citing *In re Fisher*, 427 F.2d 833, 839, 166 U.S.P.Q. 18, 24 (CCPA 1970)). Thus, the acknowledged working examples alone establish enablement of the claims. The applicable legal standard does not require that all conceivable embodiments encompassed by the claims have been demonstrated by working example.

The references cited in the Action further do not demonstrate the non-enablement of the claims and in fact support enablement. The Green (1975) reference establishes "success" in using immature maize embryos as a source of callus as of at least 1975. The Action states that the reference mentions certain failures as well, such as "the failure of explants such as shoots, flowers and mature embryos to produce callus capable of regenerating whole plants." However, the current claims are directed to intact *regenerable* maize cells and therefore exclude non-regenerable cells. Further, the reference demonstrates a high level of skill in the art for tissue culture generally and that those of skill in the art knew how to determine which cells were regenerable. This demonstrates that, at best, identification of further intact regenerable maize cells for use with the invention requires routine experimentation, which is irrelevant to enablement given the applicable legal standard of *undue* experimentation. *In re Wands*, 858 F.2d

731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). Courts have noted that in fields such as this where the art typically engages in experimentation even complex experimentation is not necessarily undue. *In re Certain Limited-Charge Cell Culture Microcarriers*, 221 USPQ 1165, 1174 (Int'l Trade Comm'n 1983), *aff'd. sub nom., Massachusetts Institute of Technology v. A.B. Fortia*, 774 F.2d 1104, 227 USPQ 428 (Fed. Cir. 1985). Finally, the relevancy of the teaching of Green (1975) to the current claims in any negative regard is questionable at best given its 1975 publication date.

The Green (1982) reference does not contradict enablement as it establishes no more than that embryogenic maize callus has advantages. No suggestion is made in the Action that it teaches the inoperability of any intact regenerable maize cells. Similarly, the Vasil (1987) and Rhodes *et al.* (1988) references concern protoplasts, not the intact regenerable cells required by the current claims, and thus are irrelevant to enablement of the instant claims. Finally, Potrykus (1990) is cited for the proposition that obtaining whole transformed plants requires embryogenic cells that are competent for transformation and plant generation, in apparent contrast to shoot meristems. Again, at best, the reference can be deemed to suggest that shoot meristems do not work. However, this and the other references in fact demonstrate that experimentation was common in the art and those of skill in the art knew how to conduct such experiments. Further, the presence of inoperative embodiments does not necessarily render a claim nonenabled. *Atlas Powder Co. v. E.I. du Pont de Nemours & Co.*, 750 F.2d 1569, 1577 (Fed. Cir. 1984). Given the level of skill in the art, limitation of claims to intact regenerable cells and teaching in the specification, the claims have been fully enabled.

In view of the foregoing, Applicants submit that the claims are of a proper scope and therefore respectfully request removal of the rejection under 35 U.S.C. §112, first paragraph.

C. Rejections Under 35 U.S.C. §112, Second Paragraph

The Action has rejected claims 10-32 under 35 U.S.C §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter the Applicants regard as the invention. Applicants respond to each rejection of claims 10-32 below.

The Action alleges that claim 10 is indefinite in that the DNA in step (ii) that comprises the preselected DNA sequence in step (i) cannot be expressed unless the cells comprising it are identified in step (ii). In response, Applicants have amended claim 10. As the amended subject matter was inherent in the original claim, Applicants have not disclaimed any subject matter through the amendment. It is believed that the rejection is moot in light of the amendment.

The Action alleges that claims 16-18 are unclear regarding the sequence encoding the HD73, HD1 or DH1 endotoxins. In response, Applicants have amended claims 16-18. It is believed that the rejection is moot in light of the amendment.

The Action alleges that claim 19 is unclear regarding the location of the promoter. In response, Applicants have amended claim 19. It is believed that the rejection is moot in light of the amendment.

The Action alleges that claim 20 lacks a basis regarding the location of the promoter. In response, Applicants have amended claim 20. It is believed that the rejection is moot in light of the amendment.

The Action alleges that claims 20 and 25 lack antecedent basis for the DNA sequence encoding said endotoxin. Applicants traverse this rejection. Applicants point out that claim 20 depends from claim 19, which depends from claim 10 or 11 and that claim 11 further depends from claim 10, the base claim. Step (i) of claim 10 recites "....wherein said DNA comprises a

preselected DNA sequence encoding a ...endotoxin...." In addition, Applicants point out that claims 16 and 17, from which claim 25 also depends recite "...wherein the preselected DNA sequence encodes ...endotoxin...." Thus, there is clearly antecedent basis for "the DNA encoding said endotoxin" in both claim 20 and claim 25. Applicants therefore respectfully request removal of this rejection.

The Action alleges that claim 21 is unclear regarding the preselected DNA sequence comprising a selectable marker gene. Applicants respectfully traverse this rejection. Claim 21 depends from claim 11 which recites "...wherein the preselected DNA sequence further comprises a selectable marker gene...." Thus, it is clear that the preselected DNA sequence comprises a selectable marker gene. Applicants therefore respectfully request removal of this rejection.

The Action alleges that claims 23 and 24 lack antecedent basis for "the compound." In response, Applicants have amended claims 23 and 24. It is believed that the rejection is moot in light of the amendment.

The Action alleges that the term "increased" in claim 25 renders the claim indefinite. In response, Applicants have amended claim 25. Support for amendment to this claim may be found in claim 10. It is believed that the rejection is moot in light of the amendment.

The Action alleges that claim 26 lacks antecedent basis for "the DNA encoding the *Bacillus thuringiensis* endotoxin." Applicants traverse the rejection but note that claim 26 has been amended in the interest of compact prosecution. It is believed that the rejection is moot in light of the amendment.

The Action alleges that claim 27 lacks antecedent basis for "the truncated *Bacillus thuringiensis* endotoxin." In response, Applicants have amended claim 27. It is believed that the rejection is moot in light of the amendment.

The Action alleges that claims 28-29 lack antecedent basis for "the preselected DNA." Applicants traverse this rejection but note that claims 28-29 have been amended in the interest of compact prosecution. It is believed that the rejection is moot in light of the amendment.

The Action further alleges that claim 29 lacks antecedent basis for "the DNA encoding the endotoxin." Applicants traverse this rejection. Applicants point out, as discussed above, that claim 29 depends from claim 19 which depends from claim 10, the base claim which clearly recites "...wherein said DNA comprises a preselected DNA sequence encoding a ...endotoxin..." Thus, there is antecedent basis for "the DNA encoding said endotoxin." Applicants therefore respectfully request removal of the rejection of this claim.

The Action alleges that claim 30 is unclear regarding the location of the promoter relative to the DNA sequence encoding the endotoxin and to the promoter recited in claim 19. In response, Applicants have amended claim 27. It is believed that the rejection is moot in light of the amendment.

In light of the foregoing, Applicants submit that claims 10-32 are definite and therefore respectfully request removal of the rejection of the claims under 35 U.S.C. § 112, second paragraph.

D. Rejection of Claims Under the Judicially-Created Doctrine of Obviousness-Type Double Patenting

(1) The Action rejects claim 32 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 5,484,956 in view of Adang *et al*. (US 5,380,831, filed September 1988).

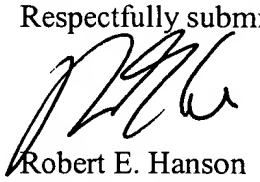
(2) The action also rejects claims 11-32 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 50-51 and 57-58 of copending Application No. 07/508,045 now U.S. Patent No. 5,484,956.

In response, Applicants note that a terminal disclaimer will be submitted over U.S. Patent No. 5,484,956 upon an indication that the claims are otherwise allowable. Removal of the rejection is thus respectfully requested.

E. Conclusion

In light of the foregoing, applicants submit that all claims are in condition for allowance, and an early indication to that effect is earnestly solicited. The examiner is invited to contact the undersigned (512) 536-3085 with any questions, comments or suggestions relating to the referenced patent application.

Respectfully submitted,



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Date: March 24, 2004